20. (Amended) An eyedropper, comprising:

a hollow cylindrical barrel comprising a first end, a second end, and an inner surface;

a means for providing suction to draw an aqueous formulation into the hollow cylinder barrel, the first end of the barrel configured to receive the means for providing suction to draw the formulation, the barrel having a small opening at the second end configured to permit passage of the formulation;

wherein the formulation comprises an aqueous solvent and a compound comprising an alpha 1 antagonist capable of interfering with a biochemical reaction which results in stimulation of dilator muscles of a human eyes.

21. (Amended) The eyedropper of claim 20, wherein the inner surface of the barrel surrounds a volume of five cubic centimeters or less.

Please cancel Claim 2 without prejudice or disclaimer.

REMARKS

In the Office Action, Claims 1-6 and 19 are rejected under 35 U.S.C. § 112, first paragraph; Claims 13-15 are rejected under 35 U.S.C. § 112, second paragraph; Claims 1, 2, 5-17, and 18 are rejected under 35 U.S.C. § 102; and Claims 20 and 21 are rejected under 35 U.S.C. § 103. Claims 1, 13 and 16-21 have been amended; and Claim 2 has been canceled.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with Markings t Show Changes Made**." Applicant respectfully submits that the rejections have been overcome or are improper in view of the amendments and for the reasons set forth below.

In the Office Action, Claims 1-6 and 19 have been rejected under 35 U.S.C. § 112, first paragraph. As previously discussed, independent Claims 1 and 16 have been amended to include the alpha 1 antagonist feature. Claims 3-6 and 17-19 each depend from independent Claims 1

and 16, respectively and thus incorporate each of the features of the respective independent claim as a matter of law. Therefore, Applicant believes that the claimed invention fully complies with 35 U.S.C. § 112, first paragraph.

Accordingly, Applicant respectfully requests that this rejection be withdrawn.

In the Office Action, Claims 13-15 have been rejected under 35 U.S.C. § 112, second paragraph. As previously discussed, independent Claim 13 has been amended to recite a method of eye treatment. As fully supported in the Specification, the present invention, in an embodiment, can be useful in treating patients who have been subjected to various types of refractive eye surgery. Because such surgery can increase the degree of light scatter the administration of the formulation of the invention can modulate this effect by contracting the pupil. *See*, Specification, page 9, lines 4-8. Claims 14 and 15 depend from Claim 13 and thus as a matter of a law incorporate each of the features of newly amended and independent Claim 13. Therefore, Applicant believes that the claimed invention fully complies with 35 U.S.C. § 112, second paragraph.

Accordingly, Applicant respectfully requests that this rejection be withdrawn.

In the Office Action, Claims 1, 2, 5-17, and 18 are rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 4,443,441 ("*Galin*"). Applicant respectfully submits that this rejection is improper.

Of the pending claims with respect to this rejection, Claims 1, 7, 13, and 16 are the sole independent claims. Independent Claim 1 recites a method of modulating pupil dilation that includes, in part, administering to an eye of a patient a formulation including an alpha 1 antagonist capable of disrupting endogenous compounds which stimulate dilator muscles of the eye. Independent Claim 7 recites a method for optimizing pupil diameter in dim light by minimizing its dilation in response to less light. The method includes administering a therapeutically effective amount of an alpha 1 antagonist to an eye of a person in need thereof. Independent Claim 13 recites a method of eye treatment that includes subjecting the eye of a human patient to refractive surgery; allowing the eye of the patient to recover; and administering to the patient a formulation that includes an alpha 1 antagonist wherein the formulation is a

liquid formulation applied directly to the eye of the patient. Independent Claim 16 recites an ophthalmic night vision formulation that includes, in part, a therapeutically effective amount of a pharmaceutically active compound that includes an alpha 1 antagonist capable of disrupting endogenous compounds which stimulate dilator muscles of a human eye.

In contrast, Applicant believes that *Galin* fails to disclose or arguably suggests a number of features of the claimed invention. *Galin* merely relates to the use of alpha adrenergic blocking agents to aid in the fixation of intraocular lenses by acting as a miotic and causing miosis or contraction of the pupil induced by paralysis or relaxation of the dilator muscle of the iris without contraction of the sphincter muscle of the iris. Indeed, *Galin* further discloses that this unique pupillary activity reduces eccentric synechia formation and lens dislocation. *See, Galin*, column 1, lines 61-67.

Applicant believes that the purported teachings of *Galin* clearly contrast the claimed invention. With respect to independent Claim 1, nowhere does *Galin* disclose or arguably suggest a method of modulating pupil dilation that includes, in part, administering to an eye of a patient a formulation that includes an alpha 1 antagonist. Applicant has discovered that pupil dilation can be modulated as such to optimize pupil diameter thereby enhancing vision. For example, the pupil diameter can be optimized to dilate no more than 5 millimeters in dim light and be constricted to no more than 1 millimeter in bright light. *See,* Specification, page 2, lines 21-26. Nowhere does *Galin* disclose or arguably suggest the modulating pupil dilation feature of Claim 1, let alone optimizing pupil diameter in dim light by minimizing its dilation in response to less light by administering a therapeutically effective amount of an alpha 1 antagonist as required by Claim 7.

Further, Applicant believes that *Galin* fails to disclose or arguably suggest treating a human eye that has been subject to refractive surgery by applying a liquid formulation directly to the eye subsequent to surgery wherein the formulation includes an alpha 1 antagonist. As previously discussed, because such refractive surgery can increase the degree of light scatter, the administration of the alpha 1 antagonist formulation can modulate this effect by contracting the pupil, thus enhancing vision. Again, *Galin* merely relates to the fixation of intraocular lenses. This is clearly deficient with respect to the eye treatment features of Claim 13. Moreover, *Galin*

is clearly deficient with respect to the ophthalmic night vision formulation features of independent Claim 16.

Based on the evident differences between *Galin* and the claimed invention, Applicant believes that *Galin* fails to disclose or arguably suggest a number features of the claimed invention. Therefore, Applicant respectfully submits that *Galin* fails to anticipate the claimed invention.

Accordingly, Applicant respectfully requests that this rejection be withdrawn.

In the Office Action, Claims 20 and 21 are rejected under 35 U.S.C. § 103 as being unpatentable over *Dougherty*. Applicant respectfully submits that this rejection is improper.

Independent Claim 20 recites an eyedropper that includes, in part, a hollow cylindrical barrel, a means for providing suction to draw an aqueous formulation into the barrel wherein the formulation includes an aqueous solvent and a compound comprising an alpha 1 antagonist capable of interfering with a biochemical reaction which results in stimulation of dilator muscles of a human eye. Claim 21 depends from Claim 20 and therefore incorporates each of the features of Claim 20 as a matter of law.

In contrast, nowhere does *Dougherty* disclose or suggest a number of features of the claimed invention. For example, Applicant believes that *Dougherty* fails to disclose or suggest the alpha 1 antagonist formulation features of the claimed invention. *Dougherty* merely relates to an eyedropper with a light source. In this regard, it places no emphasis or particularity with respect to the type of agents used with the eyedropper. As previously discussed, the alpha 1 antagonist formulations of the claimed invention can be effectively utilized to enhance vision by optimizing pupil diameter in dim light and/or bright light. Based on the purported teaching of *Dougherty*, Applicant believes that one skilled in the art would not be inclined to modify *Dougherty* to include the alpha 1 antagonist formulation features of the claimed invention. Therefore, Applicant respectfully submits that *Dougherty* fails to render obvious the claimed invention.

Accordingly, Applicant respectfully requests that this rejection be withdrawn.

For the foregoing reasons, Applicant respectfully requests reconsideration of the patent application and earnestly solicits an early allowance of same.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1, 4, 13, and 16-21 have been amended as follows:

1. (Amended) A method of modulating pupil dilation, comprising:

administering to an eye of a patient a formulation comprising ~~a compound characterized by its ability to~~an alpha 1 antagonist capable of disrupting endogenous compounds which stimulate dilator muscles of the eye; and

allowing the formulation to remain in contact with the eye for a period of time and under lighting conditions where the dilator muscles would be stimulated in the absence of the formulation.

4. (Amended) The method of claim ~~3~~1, wherein the compound characterized by its ability to reduce eye redness is tetrahydrazolene.

13. (Amended) A method of eye treatment, comprising:

subjecting the eye of a human patient to refractive surgery;

allowing the eye of the patient to recover; and

administering to the patient a formulation comprised of an alpha 1 antagonist wherein the formulation is a liquid formulation applied directly to the eye of the patient.

16. (Amended) An ophthalmic, night vision formulation, comprising:

a sterile aqueous carrier; and

a therapeutically effective amount of a pharmaceutically active compound ~~characterized by its ability to~~comprising an alpha 1 antagonist capable of disrupting endogenous compounds which stimulate dilator muscles of a human eye.

17. (Amended) The ophthalmic formulation of claim ~~1~~16, wherein ~~the compound which disrupts endogenous compounds which stimulate dilator muscles is an alpha 1 antagonist and~~ the formulation further comprises tetrahydrazolene.

18. (Amended) The formulation of claim ~~17~~16, wherein the alpha 1 antagonist is selected from the group consisting of a phenoxybenzamine and a phentolamine.

19. (Amended) The formulation of claim ~~17~~16, wherein the alpha 1 antagonist is present in a concentration in a range of from about 0.01 milligrams per cubic centimeter of solvent to about 50 milligrams per cubic centimeter of solvent and wherein the solvent comprises an ophthalmic artificial tear solution.

20. (Amended) An eyedropper, comprising:

a hollow cylindrical barrel comprising a first end, a second end, and an inner surface;

a means for providing suction to draw an aqueous formulation into the hollow cylinder barrel, the first end of the barrel configured to receive the means for providing suction to draw the formulation, the barrel having a small opening at the second end configured to permit passage of the formulation;

wherein the formulation comprises an aqueous solvent and a compound ~~characterized by its ability to~~ comprising an alpha 1 antagonist capable of interfereing with a biochemical reaction which results in stimulation of dilator muscles of a human eyes.

21. (Amended) The eyedropper of claim 20, wherein the inner surface of the barrel surrounds a volume of five cubic centimeters or less ~~and the compound is an alpha 1 antagonist.~~

Claim 2 has been canceled without prejudice or disclaimer.